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|-----------------|-------------|----------------------|---------------------|------------------|
| 09 836,436      | 04/17/2001  | Xiaowu Liang         | GTSYS.006A          | 5847             |

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 01/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/836,436

Applicant(s)

LIANG ET AL.

Examiner

Konstantina Katcheves

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13, 14, 16-21, 26, 27, 29-48, 53, 54 and 64-66 is/are rejected.
- 7) ☒ Claim(s) 10-12, 15, 22-25, 28, 49-52 and 55-63 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves  
January 27, 2003

  
REMY YUCEL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

### **DETAILED ACTION**

Claims 1-66 are pending in the present application. This Office Action is in response to Paper No. 8, filed 6 November 2002.

#### ***Election/Restrictions***

Applicant's election with traverse of Group in Paper No. 8 is acknowledged. The traversal is on the grounds that the method of Group II is largely similar to the method of claim 18, but written in independent form. Thus, no serious search burden is presented to the examiner. This is found persuasive, and the restriction requirement has been withdrawn. Accordingly, claims 1-66 are currently under consideration.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 13, 14, 16-21, 26, 27, 29-48, 53, 54 and 64-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (Nature Genetics Vol.20 1998).

Zhang et al. teach a method of homologous recombination using linear DNA carrying the Tn5 kanamycin resistance gene, neo, made by PCR methods. See page 123, column 1. These DNA constructs were made to have "homology arms" that are 20 to more than 60 nucleotides in length. See page 123, column 2 and figure 1. The linear DNA was co-transformed with a

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plasmid into *E. coli* strains. See figure 1. Zhang et al. teach that the products of this cloning method include a selectable gene. Zhang et al. also teach that a cassette made using PCR disrupted the lacZ gene of the plasmid. A PCR fragment having intact lacZ and homology arms then repaired LacZ. See figure 4 and page 124, column 2. Thus, lacZ, selection marker, was disabled, and then repaired by homologous recombination with linear DNA having homology arms.

Claims 1, 7, 8, 13, 14, 16, 17, 29-31, 35-37, 41-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Bradshaw et al. (Nucleic Acids Research Vol.23 no.23 1995).

Bradshaw et al. teach a method using the plasmid pClasper comprising two flanking linker sequences that can be either 20 bp or 40 bp in length. The plasmid comprising a selection element such as chloramphenicol acetyltransferase. See page 4850, column 2 and page 4852.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite the language "adapter sequences." This terminology is vague and indefinite because it raises questions as to what Applicant actually intends the term to mean.

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Is an adapter sequence flanking sequences of homology, is it flanking recombination sites, or something else entirely. Clarification is suggested.

Claim 14 appears to claim a Markush group without the proper use of the Markush format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. The metes and bounds of this Markush group is indefinite because it is unclear if the members of this group are mutually exclusive. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). Applicant states the vector "comprises a plasmid, a cosmid, and a bacterial artificial chromosome (BAC)."